**Selection of the sIRB**

Harvard University has been selected to serve as the single IRB of record (sIRB) for the research described in this proposal. All participating domestic sites have agreed to rely the Harvard University Area IRB, and any domestic sites added after the award will be required to agree to this reliance arrangement unless they meet the criteria for exception to the policy.

This document outlines Harvard University’s statement of compliance and qualifications, reliance agreement documentation plans, and the communication plan between the local sites, local IRB, lead site, and sIRB.

**Harvard University Area IRB Compliance and Qualifications**

The Harvard University Human Research Protection Program is AAHRPP accredited and oversees approximately 2,000 active human research projects primarily focused on social and behavioral sciences research and research involving all vulnerable populations described in the Common Rule. Harvard University operates 1 IRB and is supported by 9 staff members. Harvard University routinely serves as the IRB of record for many other academic institutions, and foreign and local organizations.

Harvard University’s IRB operates in compliance with all relevant federal and local regulations and is registered with FDA and OHRP. Harvard University maintains an active Federalwide Assurance (FWA) with the Office for Human Research Protections (FWA00004837). The Harvard University Area IRB can provide waivers of authorization in compliance with the HIPAA Privacy Rule.

The Harvard University Area IRB has appropriate membership, including the professional competence necessary to review the proposed research. Policies and standard operating procedures that support the role of a reviewing IRB have been established.

**Reliance Agreements**

When possible, Harvard University will utilize the SMART IRB Master Reliance Agreement to facilitate a rapid IRB review process. If sites are not signees to the SMART IRB Agreement, Harvard University can provide a similar Reliance Agreement for sites to consider that has been used successfully for many studies. Participating sites will agree upon roles and responsibilities of the sIRB and participating sites and this will be documented prior to study start. Documentation regarding the agreement and communication will be kept by both the sIRB and each participating site.

**Communication Plan**

The Harvard University Area IRB uses an online submission system which is accessible by Harvard University employees. All application materials will be submitted to the IRB by the Harvard University PI or other Harvard University study team members designated by the PI. Participating sites will provide necessary information or assurances to the Harvard University study team for submission to the Harvard University Area IRB. The Harvard University Area IRB office will communicate directly with the Harvard University study team as the proxy for all participating sites. Participating sites will follow their local procedures for dissemination of information and documentation (e.g., if the local IRB office or ancillary services require copies of the IRB approval). When appropriate, the Harvard University Area IRB office will communicate directly with participating site Human Research Protection Program offices.

The Harvard University study team, under the supervision of the lead PI, will provide coordination services to:

* Coordinate communications with partnering sites
* Request and receive information and documentation from partnering sites
* Develop template materials for review by the Harvard University Area IRB and for limited modification by participating sites
* Submit materials from all sites to the Harvard University Area IRB and coordinate responses to any IRB queries
* Provide documentation to participating sites

Participating sites will follow local procedures to coordinate, collect and verify information such as:

* Local context
* Site variations in areas such as recruiting, informed consent, HIPAA, populations
* Conflict of Interest disclosure and management
* Completion of ancillary reviews
* Training and qualifications of study team
* Continuing Review or Closure information
* Reportable Events

The lead PI will maintain a copy of this communication plan and any other communication plans that are developed. Copies will be made available to the participating sites as appropriate.